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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/554,252

01/18/2007

William C Sessa

YU/110

2742

1473 7590 04/20/2009

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PATENT DOCKETING 39/361
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EXAMINER

MERTZ, PREMA MARIA

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

04/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/554,252	Applicant(s) SESSA ET AL.	
	Examiner Prema M. Mertz	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-45 and 49-59 is/are pending in the application.
- 4a) Of the above claim(s) 39-41, 44, 45 and 49-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42 and 43, 55-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-38, 46-48 have been canceled previously. Amended claims 42, 43 (3/9/09) and new claims 55-59 (3/9/09) are under consideration by the Examiner. Claims 39-41, 44-45, 49-54, are drawn to a non-elected invention.

2. Receipt of applicant's arguments and amendments filed on 3/9/2009 is acknowledged.

3. The following previous rejections and objections are withdrawn in light of applicants amendments filed on 3/9/2009:

(i) the rejection of claims 42-43 under 35 U.S.C. 112, second paragraph.

Applicant's arguments with respect to claims 42-43, have been considered but are moot in view of the new ground(s) of rejection.

4. Applicant's arguments filed on 3/9/09 have been fully considered and were persuasive in part. The issues remaining and new issues are stated below.

Claim Rejections - 35 USC § 112, first paragraph, scope of enablement

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. Claims 42-43, 55 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating conditions characterized by pathological vascular remodeling in a subject in need thereof by administering an effective

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amount of a composition comprising Nogo-B or a fragment of Nogo-B comprising amino acids 1-200 of the N-terminus of Nogo-B, does not reasonably provide enablement for a method as recited in claim 42. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

This rejection is maintained for reasons of record set forth at pages 3-9 of the previous Office action of 10/8/2008.

Applicants argue that they have demonstrated that cell adhesion, spreading and migration can be measured in vitro at Examples 2-4 (see, e.g., page 41, line 27 -page 46, line 12), one of skill in the art using the teaching of specification could determine whether a fragment retains a biological activity selected from the group consisting of promoting endothelial cell adhesion, spreading and migration by routine experimentation. Applicants also argue that they have demonstrated that overexpression of full-length Nogo-B in wild-type blood vessels decreases intima formation after vessel injury in vivo and that overexpression of Nogo-B in Nogo-A/B (-/-) mice prevents injury-induced neointima formation in vivo at Examples 9 and 10, respectively (see, e.g., page 54, line 11 to page 59, line 5). Applicants argue that these experiments were performed using the femoral arterial injury model which is an art accepted in vivo model of pathological vascular remodeling and have cited Roque et al.(2000) in this regard. Applicants assert that having shown the effectiveness of Nogo-B in vivo in the femoral arterial injury model, the specification does provide guidance for the successful treatment of diseases or conditions characterized by pathological vascular remodeling besides ischemia. However, contrary to Applicants arguments, the data provided in the instant specification is insufficient to predict in

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vivo efficacy for treatment of diseases or conditions characterized by pathological vascular remodeling by administering fragments of Nogo-B other than a fragment of Nogo-B comprising amino acids 1-200 of the N-terminus of Nogo-B. Furthermore, contrary to Applicants arguments, independent claim 42 encompasses a method for treating all conditions or diseases characterized by vascular remodeling including arteriosclerosis by administering fragments of Nogo-B. Other than treatment of ischemia, and providing data which indicate that Nogo-B reduces undesirable vascular remodeling (see specification, pages 54-59, and Figures 9-10), the specifications fails to provide any guidance for the successful amelioration of symptoms of all pathological vascular remodeling using fragments of Nogo-B other than a fragment of Nogo-B comprising amino acids 1-200 of the N-terminus of Nogo-B. Thus, it would require undue experimentation on the part of the skilled artisan to use the claimed method for treatment as recited, in the absence of sufficient information to predict the results with an adequate degree of certainty. The recitation of "fragment of Nogo-B" in claim 42, is not commensurate with the scope of the specification. Given the breadth of claim 42 in light of the predictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of skill in the art to practice the claimed invention.

An application must be complete as filed. The instant specification as filed does not provide any guidance or examples that would enable a skilled artisan to practice a method as claimed by administering to a patient fragments of Nogo-B as claimed. Applicants are reminded that "Argument of counsel cannot take the place of evidence lacking in the record" (*In re Scarbrough*, 182 USPQ 298, 302 (CCPA 1974)).

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Claim Rejections - 35 USC § 112, second paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 56-59, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 56, line 2, recites the limitation "the step of administering...". There is insufficient antecedent basis for this limitation in the claim.

Claim 59, line 2, is vague and indefinite because it recites "...is response to an injury". It is unclear what the metes and bounds of the term "injury" are. Is it blood vessel injury, vascular smooth muscle injury or something else?

Claims 57-58 are rejected as vague and indefinite insofar as they depend on the above rejected claim 56 for their limitations.

Conclusion

No claim is allowed.

Claims 42-43, 55-59 are rejected.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on (571) 272-0835.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Prema Mertz/

Prema Mertz, Ph.D., J.D.

Primary Examiner

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